MAY - 2 2000

K000327

VISX
WE MAKE THINGS CLEAR

Summary ~~Statement~~

SUBMITTER:

Submitted by:

Company Name:	VISX, Inc.
Address:	3400 Central Expressway Santa Clara, California 95051
Phone:	(408) 773-7327
Fax:	(408) 773-7324

CONTACT PERSON: David M. Patino
Vice President, Regulatory and Clinical Affairs

DATE SUMMARY PREPARED: January 31, 2000

TRADE NAME: WaveScan™ Wavefront System Model HS 1

COMMON NAME: Autorefractor

SUBSTANTIALLY EQUIVALENT TO:

The WaveScan™ Wavefront System Model HS 1 is substantially equivalent to the predicate device, the Canon R-50m. Both devices have the same indication for use, in that they are devices which are diagnostic tools for obtaining objective output measurements of refractive error of the eye. These devices obtain this information by means of light ray deflection principles to measure the refractive elements of the eye and provide automated read-outs of refractive error. The principle of light waves incorporates the known elements of light energy moving in successive flat sheets, or wavefronts. The measurement principles of both instruments utilize the element of wavefront measurements from the refractive elements of the eye, the lens and cornea as light interference changes the wavefront as affected by these elements. Each instrument utilize condensing lenses within the body of the instrument, and a fogging technique which blurs a fixation target for the patient who is being measured. The output measures for each instrument consist of the spherical, cylindrical and axis of the subject's refractive error which are provided in a printed read-out format..

DESCRIPTION of the DEVICE:

The WaveScan™ Wavefront System Model HS 1 autorefractor device is a diagnostic instrument designed to measure refractive error of the eye automatically by use of wavefront technology. Light travels in a procession of flat sheets known as wavefronts. As these wavefronts pass through an imperfect refractive medium including the cornea and the lens, the aberrations which are created by the irregular surfaces "wrinkle" the light rays and create wavefront errors or distortions. The instrument contains tiny sensors which measure the gradient, or slope, of the wavefront which emanate from the eye. After light travels through the eye's optical system and out again, the sensors accurately detect slight variations of wavefront irregularities as they exit the eye. The sensors then provide additional information within the confines of the instrument through a series of lenses and apertures which are subject to mathematical algorithms and software. Once analyzed by the computer, a refractive error read-out is provided to the user. This analysis is made from multiple points of light which precisely pinpoint variations in refractive status across the entire entrance pupil of the eye. This allows for the high level of accuracy of the instrument thus providing the user with very precise readings of refractive error.

INDICATIONS FOR USE:

The VISX WaveScan™ System Model HS 1 is a diagnostic instrument indicated for the automated measurement and analysis of refractive errors of the eye including hyperopia and myopia from +6.00 to -8.00 diopters spherical, and astigmatism from 0.00 to -6.00 diopters.

SPECIFICATIONS OF THE DEVICE:

	VISX WaveScan
Accuracy	No Specification
Reproducibility	No Specification
Power Requirements	110/120V, 50/60Hz
Measurable Range	Sphere -8 to +6 in 0.1D increments Cylinder 0 to -6 in 0.1D increments Axis 0-180 degrees
Data Output	Print or Electronic
Approvals	ETL
Measurement Points	Up to 100 points

TESTING OF THE DEVICE:

Comparison testing was conducted under a protocol designed to demonstrate the equivalence of the WaveScan™ Wavefront Model HS 1 to the Canon Model R-50m autorefractor. These devices which are basically equivalent, measure refractive error of the eye automatically by use of scanning light deflection through the optics of the eye. The near infrared light acts as a secondary light source reflected off the back of the eye at the retina. The emerging light passes through the optics of the lens and cornea and is affected by a series of apertures and lenses which are then systematically analyzed through mathematical models and reveal the measurement of refractive error. The tests were conducted using a model test eye developed by VISX, Inc. and modeled after the Gullstrand Standard Test Eye Model established for bench testing in the ophthalmic community. Tests were conducted across a range of refractive errors including myopia, hyperopia, and astigmatic errors of refraction at various angles and orientations. Combinations of myopic and hyperopic astigmatism were employed. Each of these test conditions was repeated five times in each instrument, and subject to statistical analysis. The results indicated that the WaveScan™, Wavefront System performed within statistical 95% level of confidence in all parameters measured and was equivalent or superior to the control instrument in accuracy and repeatability. Overall, the WaveScan device provided estimates of refractive error with less variability than the control device as seen in the data, from standard deviation estimates.

LABELING

The WaveScan™ Wavefront System Model HS 1 is provided to the user with a User Manual of Operator's Instructions. The device is a diagnostic tool used by professionals and ancillary personnel in the determination of preliminary diagnostic refractive error information.

VISX, Inc.
3400 Central Expressway
Santa Clara, CA 95051
(408) 733-2020

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 2 2000

Mr. David M. Patino
Vice President, Regulatory and Clinical Affairs
VISX, Inc.
3400 Central Expressway
Santa Clara, CA 95051-0703

Re: K000327
Trade Name: WaveScan™ Wavefront System
Regulatory Class: I
Product Code: HKO
Dated: January 31, 2000
Received: February 2, 2000

Dear Mr. Patino:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of the WaveScan™ Wavefront System have not been established for use of the device as an accessory interfaced to a refractive laser for the treatment of higher order aberrations of the eye by photorefractive keratectomy (PRK), phototherapeutic keratectomy (PTK) or laser-assisted in situ keratomileusis (LASIK).

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the

Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your 510(k) premarket notification if the limitation statement above is added to your labeling, as described.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Robert R Sathing /

for David W. Feigal, Jr., M.D., M.P.H.
Acting Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K000327

Device Name: WaveScan™ Wavefront System

Indications For Use:

The VISX WaveScan™ Wavefront System is a diagnostic instrument indicated for the automated measurement and analysis of refractive errors of the eye including hyperopia and myopia from +6.00 to –8.00 diopters spherical, and astigmatism from 0.00 to –6.00 diopters.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K000327

(Optional Format 3-10-98)